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03-30-04

PTO/SB/21 (08-00)

Approved for use through 10/31/2002-OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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| | | | |
|---|-----------------------------|-------------------------------|-------------|
| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/775,780 | |
| | Filing Date | February 10, 2004 | |
| | First Named Inventor | Keren I. Hulkower et al | |
| | Group Art Unit | (TBA) | |
| | Examiner Name | (TBA) | |
| Total Number of Pages in This Submission | | Attorney Docket Number | 06244.00002 |

| ENCLOSURES (check all that apply) | | |
|---|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Petition to Make Special, 34 References, Express Mail #EV306398986US, Exp Mail Cvr sht, Return Receipt post card |
| Remarks Please charge any additional fees or credit overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed. | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | |
|--|---|
| Firm or Individual name | Banner & Witcoff Ltd. Ten South Wacker Drive, Suite 3000 Chicago, IL 60606 Robert H. Resis (Reg. No. 32,168) |
| Signature | |
| Date | March 29, 2004 |

| CERTIFICATE OF MAILING | | | |
|--|-------|-------------|-------|
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PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 130

Complete if Known

| | |
|----------------------|-------------------|
| Application Number | 10/775,780 |
| Filing Date | February 10, 2004 |
| First Named Inventor | Hulkower et al. |
| Examiner Name | (TBA) |
| Art Unit | (TBA) |
| Attorney Docket No. | 06244.00002 |

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None
Order

☒ Deposit Account:

Deposit
Account
Number

19-0733

Deposit
Account
Name

Banner & Witcoff, LTD.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, except for the filing fee
to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |
| SUBTOTAL (1) | | | | | (\$ 0) |

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | | | | | | | | | | |
|--------------------|--|----|---|--------------|---|---|----------------|--|---|----------|---|
| Total Claims | | ** | = | Extra Claims | 0 | X | Fee from below | | = | Fee Paid | 0 |
| Independent Claims | | ** | = | 0 | X | | | | = | 0 | |
| Multiple Dependent | | | | | X | | | | = | 0 | |

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 | |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 | |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid | |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent | |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent | |
| SUBTOTAL (2) | | | | | (\$ 0) |

*or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet. | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | 130 |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17 (q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR § 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR § 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 130)

SUBMITTED BY

Complete (if applicable)

| | | | | | |
|-------------------|-----------------|-----------------------------------|----------------|-----------|----------------|
| Name (Print/Type) | Robert H. Resis | Registration No. (Attorney/Agent) | 32,168 | Telephone | (312) 463-5000 |
| Signature | | Date | March 29, 2004 | | |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**CERTIFICATE OF MAILING
(PATENT)**

Express Mail No. EV306398986US

Deposited March 29, 2004

I hereby certify that the attached correspondence, identified below, is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Mail Stop Petition, Alexandria, VA 22313-1450.

By: _____

| | |
|------------------------|---|
| Patent Application of: | Hulkower et al. |
| Title: | Method and Apparatus for Detecting an Analyte |
| Serial No. | 10/775,780 |
| Attorney Docket No. | 06244.00002 |

- ☒ Transmittal Form, (in duplicate)
- ☒ Fee Transmittal (in duplicate)
- ☒ Petition to Make Special
- ☒ 34 References
- ☒ Return Receipt Postcard



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the U.S. Patent Application of

SIEGEL et al.

Examiner: Unassigned

Serial No.: 10/794,978

Art Unit: 3743 (proposed)

Date Filed: March 5, 2004

Docket No.:D-0309 DIV

For: **BENCH TOP GRILL ASSEMBLY**

Mail Stop - **PETITION**

Director of Patents

U.S. Patent Office

P.O. Box 1450, Alexandria, VA 22313-1450

**PETITION TO MAKE SPECIAL
FOR ACTUAL INFRINGEMENT (37 CFR §1.102 and MPEP §708.02)**

Applicant hereby petitions to make this application special because of actual infringement.

1. **Accompanying Material**

Accompanying this petition is:

- (A) A Statement of Facts in Support of Petition to Make Special Because of Actual Infringement, AND
 - (B) A Statement by Attorney in Support of Petition to Make Special Because of Actual Infringement. (Including the present Information Disclosure Statement and PTO-1449, with copies of each of the references cited)
2. **Fee (37 CFR §1.17(I) - 130.00)**
Attached is a check in the amount of \$130.00, and if this amount is insufficient, authorization is provided to the USPTO to charge any remainder due or credit any over payment, to Deposit Account 10-0100.
3. A duplicate of this paper is provided.

03/31/2004 ANQB11 00000106 10794978

130.00 DP
01 FC:1460

That The Specifically Designated Search Areas Included:

D7 Equipment for preparing or serving food or drink not elsewhere specified

 Warming or Cooking

332 . Solid or liquid fuel outdoor type

 .. Masonry type

 .. Mobil Unit

 .. Unitary Vertical Support Column

 ... Cantilevered Cooking Surface

337 .. Table Top Type

Specific Utility Areas from 1976 to date electronically and 1960 manually

Class 126 - Stoves and Furnace

Sub Class

9R

25R

41R

43

44

Class 99 - Food and Beverages: Apparatus

385, 401 Cooking, Slice Toaster or Broiler, with Heat Distribution

(D) That a rigid comparison of the alleged infringing product(s) with the claims of the application has been made and it is the opinion of the undersigned registered and practicing patent attorney in good standing that some of the claims are unquestionably infringed.

We have been able to obtain actual specimens of two infringing assemblies. In our present opinion, the infringing devices themselves, as clearly embodied and as portrayed in packaging materials for each are simple in basic construction, and as is evident from reviewing the specimens and promotional materials, are virtually identical in scope to that claimed by the scope of at least one of the pending independent claims.

In sum, the undersigned practitioner asserts that in his opinion some of the claims are unquestionably infringed and the rights resulting from the present application are mandatory to prevent continued damaging infringement. Consequently, it is clear the undersigned that actually infringement exists for at least some of the claims both literally and under the doctrine of equivalents.

To wit, the undersigned makes a clear statement under 18 U.S.C. §1001 that he is an attorney registered to practice before the office, that he holds a power of attorney in the present matter, and that he believes after analysis and review that, the infringing assemblies unquestionably includes elements noted in at least one of the independent claims and hence infringes at least one independent claim.

MPEP §708.02(II) does not appear to require providing a comparison claim chart and so none is provided. A photo of the infringing packaging materials, clearly showing a photo of the infringing assembly is also not included since MPEP §708.02 (II) dictates that "models or specimens of the

infringing product or the application should not be submitted unless requested." Should the Office request such a comparison or a copy of the materials clearly showing the infringing assembly they will be provided promptly.

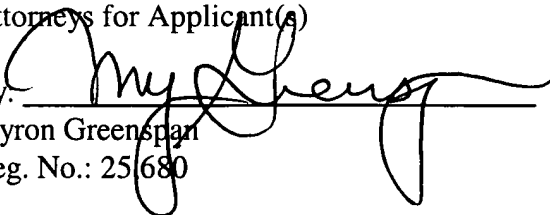
Dated: 3/26/04

Lackebach Siegel, LLP
One Chase Road
Scarsdale, NY 10583
Telephone: 914 723 4300
MG/afy

P-0309 DIV. Atty stmt on pet to make special.wpd

Respectfully submitted,

LACKENBACH SIEGEL, LLP
Attorneys for Applicant(s)

By: 
Myron Greenspan
Reg. No.: 25680



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the U.S. Patent Application of

Siegel et al.

Examiner: Unassigned

Serial No.: 10/794,978

Art Unit: 3743 (proposed)

Date Filed: March 5, 2004

Docket No.:P-0309 DIV

For: **BENCH TOP GRILL ASSEMBLY**

Mail Stop - Petition
Director of Patents, U.S. Patent Office
P.O. Box 1450, Alexandria, VA 22313-1450

**STATEMENT IN SUPPORT OF PETITION TO MAKE SPECIAL
FOR ACTUAL INFRINGEMENT (MPEP §708.02)**

SIR:

I make the following statements in Support of our Petition to Make Special Because of Actual Infringement under MPEP §708.02(II) (A-C).

(A) That I am one of the practitioner's in this case and, am listed on the signed Declaration and Power of Attorney in this matter.

(B) That there is an infringing device and product actually on the market.

(C) That I have caused to be made a search of the pertinent prior art as noted in the accompanying Information Disclosure Statement under (MPEP §609) and form PTO-1449 filed in this application herewith, along with a complete copy of each of the references noted. I further assert that prior to filing an initial patenability search was solicited from a professional search agent covering dates previous to March 2, 2003. The contents of this search are incorporated herein. An additional search was conducted by and solicited from a professional search agent covering the dates of March 2, 2003 to the near present and the contents of this second search are similarly incorporated herein in an Information Disclosure Statement under §1.56 and a PTO-1449. A third brief search was conducted previous to February 16, 2004 and the results are similarly incorporated herein.

Applicant hereby petitions that any and all extensions of time of the term necessary to render this response timely be granted. COSTS FOR SUCH EXTENSION(S) AND/OR ANY OTHER FEE DUE WITH THIS FEE DUE WITH THIS PAPER THAT ARE NOT FULLY COVERED BY AN ENCLOSED CHECK MAY BE CHARGED TO DEPOSIT ACCOUNT #10-0100.

Date:

3/26/04

Lackebach Siegel LLP

One Chase Road

Scarsdale, NY 10583

Telephone: 914 723 4300

MG/afy

P-0309 DIV.Pet to Make Special.wpd

Attached:

Statement/Declaration of Facts - Signed

Statement/Declaration by Attorney - Signed

IDS and PTO-1449 forms

Copy of any references deemed most closely related to the present subject matter.

Respectfully submitted,

LACKENBACH SIEGEL LLP

Attorneys for Applicant(s)

By:

Myron Greenspan
MYRON GREENSPAN

Reg. No. 25,680

Certificate of Deposit by Mail

I hereby certify that this correspondence is being filed by depositing same in an envelope stamped first-class mail, addressed to the Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, in a duly marked U.S. Postal Service drop box, with appropriate postage, on the following date:

Adrienne Shirley

Name

Adrienne Shirley

Signature

3/29/2004

Date



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 06244.00002)

PATENT

In the Application of:

Keren I. Hulkower et al.

Serial No. 10/775,780

Filed: February 10, 2004

For: **Method and Apparatus for Detecting an Analyte**

Before the Examiner: (TBA)

Group Art Unit
(TBA)

PETITION TO MAKE SPECIAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

Applicants respectfully petition to make the above-cited application special for accelerated examination pursuant to 37 CFR 1.102 and MPEP 708.02 (VIII). The above-cited application has not received any examination by the examiner. The Patent Office is authorized to charge the required fee for this petition to make special as set forth in 37 CFR 1.17(h) to Account No. 19-0733. All of the claims are directed to a single invention, or if the Office determines that all of the claims presented are not obviously directed to a single invention, the Applicants will make an election without traverse as a prerequisite to the grant of special status. A pre-examination search was made by a prior art search firm, listing the field of search by class and subclass, publication, Chemical Abstracts, foreign patents, etc. The field of Search included:

03/31/2004 ANABI1 00000103 190733 10775780
01 FC:1460 130.00 DA

FIELD OF SEARCH

| <u>CLASS</u> | <u>SUBCLASS</u> |
|--------------|---|
| 435 | 4, 7.1, 7.4, 7.5, 7.72, 7.9, 7.92, 7.93, 7.94, 7.95, 10, 12, 287.1, 287.2, 287.7, 287.8, 287.9, 288.1, 288.2, 288.3, 288.4, 970 |
| 436 | 518, 531, 532, 543, 544, 800, 807, 808, 809, 810 |

Attached is a copy of each reference found in the search (Reference Nos. 1-29), and a copy of U.S. Patent Nos. 6,368,558 and 6,495,102, and U.S. Patent Application Nos. US 2003/0129085 A1, US 2003/0143112 A1, and US 2003/0166298 cited in the application (Reference Nos. 30-34). The following is a detailed discussion of the references, which identifies with the particularity required by 37 CFR 1.111 (b) and (c), how the claimed subject matter is patentable over the references.

1. U.S. Patent No. 3,145,086 discloses a unique combination of a urease system with an indicator system which offers a superior means for testing biological fluids for their urea content. This unique combination comprises an enzyme system having urease activity, a buffer, an indicator material which is capable of changing color in the presence of a pH change and preferably an agent to facilitate the suspension and distribution of the enzyme throughout the mixture. In a preferred embodiment bibulous cellulose strips are impregnated with this

competition and then dried. This product represents an important improvement in more accurately determining the quantity of urea in a specimen. When the test area of this test strip is smeared with a drop of blood, for determining the blood urea present, the enzyme system having urease activity hydrolyzes the urea present to form a reaction product (ammonium carbonate) formed will cause varying increments of pH increase. Thus critical adjustment of the amount of buffer used will result in indicator color changes which are an index of the amount of reaction product formed and therefore of the amount of urea originally present in the test sample. With this unique combination, urea present in a test specimen is indicated by the formation, in a test strip contacted with the specimen, of a clearly perceptible color change in the indicator which may be correlated with the urea concentration present in the test specimen.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

2. U.S. Patent No. 3,461,036 discloses an improved test composition, device and method for detecting urea in aqueous fluids comprising urease, a pH indicator and an ammonium-ion producing buffer for controlling the pH of the test composition. The test composition is preferably incorporated with a carrier member such as bibulous filter paper.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing

a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

3. U.S. Patent No. 3,527,674 discloses a substantially anhydrous, solid assay materials for the determination, inter alia, of reagent for assaying urea, are rendered storage stable by the presence of certain polyhydric compounds preferably mannitol, sorbitol, lactose or polyvinyl alcohol.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

4. U.S. Patent No. 3,530,040 discloses an improved test composition, device and method for colorimetrically detecting urea in aqueous fluids comprising urease, a pH indicator, a buffer for controlling the pH of the test composition, and, as a color stabilizer a combination of albumin and a heteropolysaccharide. The test composition is preferably incorporated with a carrier member such as bibulous paper.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than

a response of the analyte when exposed to the at least two dyes.

5. U.S. Patent No. 3,592,741 discloses a method for determining urea comprising the incubation of the sample containing urea in a buffered solution containing urease and nitropruside, followed by the addition of a source of phenate ion and a source of hypochlorite ion in an alkaline medium to produce a color reaction.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

6. U.S. Patent No. 3,873,269 discloses a colorimetric indicator for the determination of urea, comprising a reaction system containing urease and a colorimetric pH indicator system arranged one above the other on absorbent supports. The reaction system is characterized by containing alkali carbonate and/or hydroxide and optionally one or more organic acids, and by having a pH range of about 8 to 10.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

7. U.S. Patent No. 3,917,453 discloses a diagnostic test device comprising an absorbent medium and a reaction zone located between superposed sheets. The fluid containing the substance to be analyzed is placed on the absorbent medium. Compressive force is applied to the absorbent medium providing a predetermined quantity of fluid to the reaction zone where reagents are located to react with the substance to provide a colorimetric determination of the presence and/or concentration of the substance.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

8. U.S. Patent No. 3,950,226 discloses the ease and speed of known enzymatic assays of micro-amounts of urea is improved by a novel reagent assay comprising: urease, buffers, and an indicator dye, the improvement wherein a mixed buffer system is present which mitigates against the effects of temperature changes during the assay, and a novel method of determining released ammonia with an indicator dye and spectrophotometer.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

9. U.S. Patent No. 4,101,382 discloses the ease and speed of known enzymatic assays of micro-amounts of urea is improved by a novel reagent assay comprising: urease, buffers, and an indicator dye, the improvement wherein a mixed buffer system is present which mitigates against the effects of temperature changes during the assay, and a novel method of determining released ammonia with an indicator dye and spectrophotometer.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

10. U.S. Patent No. 4,590,157 discloses a method and test kit for detecting the presence of antigens or antibodies in a sample by an enzyme-linked immuno-sorbent assay using urease as the enzyme, urea as the enzyme substrate and di-bromo-o- cresolsulfonphthalein as the indicator.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

11. U.S. Patent No. 5,037,736 discloses a process for the determination of an analyte in a body fluid, in which there are used two binding components capable of specifically binding with one another, one of the binding components being enzyme-labelled and not carrier-fixed and the other binding component being carrier-fixed. The process contains a step in which the binding components are incubated with one another so that binding reaction takes place. The amount of enzyme-labelled binding component not bound to the carrier-fixed binding component is a measure of the concentration of the analyte which is determined by allowing the labelling enzyme to act upon a substrate producing a detection signal. During the specific binding reaction, incubation is carried out simultaneously with a non-fixed substrate of the labelling enzyme which does not produce a detection signal and with a carrier-fixed substrate of the labelling enzyme which produces a detection signal, the substrate not producing a detection signal being so chosen with regard to the amount used and affinity to the labelling enzyme in relation to the amount of the substrate producing a detection signal and its affinity to the labelling enzyme and in relation to the total activity of the labelling enzyme that the enzyme-catalyzed reaction of the substrate producing a detection signal is delayed until the specific binding reaction between the binding components has substantially taken place.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

12. U.S. Patent No. 5,139,934 discloses a method for enzyme immunoassay of a

ligand includes urease as a label. A bound fraction of ligand and antiligand conjugated to urease is formed on a solid support. The urease component of the bound fraction is contacted with a substrate composition for urease which includes a compound converted to ammonia by the urease, a tetrazolium salt and a pH dependent reducing agent which reduces the tetrazolium salt when the pH of the assay medium has been raised by the ammonia. The tetrazolium salt is reduced to a colored insoluble formazan which precipitates as a detectable spot on the support. The invention includes the substrate composition and a kit of materials for performing the assay.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

13. U.S. Patent No. 5,286,624 discloses an integral multilayer analytical element for the determination of ammonia or an ammonia-producing substance comprising a light-transmissive liquid-impermeable support, an indicator layer containing an indicator which produces a detectable change by gaseous ammonia, a liquid permeation barrier layer, a reagent layer containing an alkaline buffer and optionally a reagent capable of reacting with a substance to produce ammonia and a spreading layer laminated in this order, which is improved by that the indicator layer contains a polyvinyl alkyl ether, and/or which is improved by that the surface of said support facing toward the indicator layer is undercoated with a polyvinyl alkyl ether, a hydroxyalkyl cellulose, an alkyl cellulose, polystyrene, a polyalkyl methacrylate, polyvinylidene chloride, polyvinyl alcohol or polyvinyl pyrrolidone, substantially not containing ammonia and

ammonium ion. By using the above analytical element, ammonia or an ammonia-producing substance can be analyzed at a high coloring optical density and a high accuracy. The measuring accuracy is further improved by lowering the background optical density.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

14. U.S. Patent No. 5,314,804 discloses a rapid method and easy to use unitized test device for determining the presence of *Helicobacter pylori* in a biological tissue specimen by detecting the presence of urease in the tissue. The system basically utilizes a multilayer test device for separating and optimizing the various reactions involved, i.e. the urease in the specimen with a substrate and the ammonia generated thereby with an indicator element.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

15. U.S. Patent No. 5,328,831 discloses a substrate composition for use in a solid phase enzyme assay for urease or in a solid phase enzyme immunoassay which includes urease

as a label. The substrate composition includes a compound converted by urease to ammonia and a pH dependent reducing agent which reduces a tetrazolium salt when the pH of the medium has been raised by the ammonia produced. The tetrazolium salt may optionally be included in the substrate composition. Reduction of the tetrazolium salt produces a colored insoluble formazan which precipitates on the solid phase as an indication of the presence of urease.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

16. U.S. Patent No. 5,370,994 discloses a method for detecting urea in a liquid sample in which urease is adsorbed on a solid support such as a membrane and contacted with a solution suspected of containing urea, a pH-dependent reducing agent and a tetrazolium salt. When urea is present in the solution, the adsorbed urease converts it to ammonia, thus raising the pH and causing the pH-dependent reducing agent to reduce the tetrazolium salt to an insoluble colored formazan. The formazan precipitates as a detectable spot on the solid support, indicating the presence of urea in the liquid sample.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

17. U.S. Patent No. 5,420,016 discloses a rapid method and easy to use unitized test device for determining the presence of *Helicobacter pylori* in a biological tissue specimen by detecting the presence of urease in the tissue. The system basically utilizes a multilayer test device for separating and optimizing the various reactions involved, i.e. the urease in the specimen with a substrate and the ammonia generated thereby with an indicator element.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

18. U.S. Patent No. 5,439,801 discloses an improved test composition for the diagnosis of gastric disease by detecting the presence of urease associated with *H. pylori* in a biopsy specimen is described in which the hydrolysis of urea by urease is detected by a combination of at least two dye indicators showing a color change and a positive result at an acid pH, in which the positive color is distinctive from the color of the biopsy specimen, and in which most positive results occur in 2-10 minutes and all occur in no more than 4 hours. Specific compositions are disclosed.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing

a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

19. U.S. Patent No. 5,556,743 discloses a dye is covalently bound to a polymeric film, especially a polyhydric polymer, for assays and other purposes. The dye may be one which, when it comes into contact with hydrogen peroxide, changes color to indicate the presence of hydrogen peroxide. This dyed film may be used in qualitative or quantitative assays. This method chemically immobilizes dyes on support matrices with much higher yields of immobilized dye than has heretofore been possible. The covalently immobilized dye may be immobilized on solid matrix particles and combined with a free-flowing dye component to form a two component dye system. By combining a dyed film-former with a film-opener, the amount of dye available for assay is greatly enhanced. This provides a dye system which can be used to detect and measure quantitatively, accurately and precisely high levels of hydrogen peroxide. These high levels of hydrogen peroxide may result from the enzyme-mediated decomposition of various analytes from undiluted whole blood samples.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

20. U.S. Patent No. 5,620,900 discloses an absorptive support and a method for the determination of ammonium ions in aqueous solutions by the Berthelot method using one absorptive support. The absorptive support is impregnated with a phenol derivative.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

21. U.S. Patent No. 5,721,111 discloses a method for stabilizing urease in an assay reagent for determination of urea nitrogen in a sample and a method for accurately determining urea nitrogen in a sample. After urea nitrogen in the sample is reacted with urease in the presence of an organic boron compound, the amount of ammonia formed by the reaction is determined.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

22. U.S. Patent No. 5,731,158 discloses a method to catalyze reporter deposition to improve detection or quantitation of an analyte in a sample by amplifying the detector signal which comprises reacting an analyte dependent enzyme activation system with a conjugate

consisting of a detectably labeled substrate specific for the enzyme system, said conjugate reacts with the analyte dependent enzyme activation system to form an activated conjugate which deposits substantially wherever receptor for the activated conjugate is immobilized, said receptor not being reactive with the analyte dependent enzyme activation system. In another embodiment the invention concerns an assay for detecting or quantitating the presence or absence of an analyte in a sample using catalyzed reporter deposition to amplify the reporter signal.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

23. U.S. Patent No. 5,994,091 discloses sensor devices for use in assaying for a substance selected from (i) enzymes capable of producing a change in their environment as a result of catalytic reaction with a substrate and (ii) substrates for such enzymes is described, the devices comprising an optical waveguide having immobilized directly or indirectly on a discrete region ("the measurement region") of one longitudinal surface thereof a species whose optical properties change as a result of the aforementioned change in its environment together with the member of an enzyme substrate/enzyme pair complementary to the substance under assay. Methods of assay using such devices are also described.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing

a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

24. U.S. Patent No. 6,228,605 discloses a method for the in vivo detection of urease-producing *Helicobacter* in the upper stomach. The dense carrier is divided into two separate groups which are combined with separate reagent indicators, one of which also contains urea. The carriers are food soluble products, preferably sugar beads having a diameter of approximately 0.2 to 3.0 mm. The treated carriers and urea are encapsulated in a soluble capsule which is administered to a patient. The density of the carriers cause the capsule to migrate to the gastric mucosa, where the capsule, but not the reagents, is dissolved, placing the reagents and urea in direct contact with the gastric mucosa. The urea reacts with any urease present in the stomach by creating ammonia, which increases the pH in the immediate vicinity of the urea containing carrier and indicator beads. The two reagents react differently, through color change, to the increase in pH, which is viewed through use of an endoscope. A preferred first reagent is bromothymol blue (dibromothymolsulfonphthalein), which changes yellow in the presence of urease, and a preferred second reagent is phenol red (phenolsulfonphthalein), which turns red in the presence of urease.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

25. U.S. Patent No. 6,368,558 discloses a system for having an array comprising at least a first dye and a second dye in combination and having a distinct spectral response to an analyte. In one embodiment, the first and second dyes are from the group comprising porphyrin, chlorin, chlorophyll, phthalocyanine, or salen. In a further embodiment, the first and second dyes are metalloporphyrins. The reference states that the disclosed invention is particularly useful in detecting metal ligating vapors. The reference states that the disclosed array can be connected to a visual display device.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

26. U.S. Patent No. 6,468,759 discloses methods and compositions for the direct detection of membrane conformational changes through the detection of color changes in biopolymeric materials. In particular, the reference states that the disclosed invention allows for the direct colorimetric detection of membrane modifying reactions and analytes responsible for such modifications and for the screening of reaction inhibitors.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

27. U.S. Patent No. 6,479,278 discloses a method for the in vivo detection of urease-producing helicobacter in the upper stomach. The dense carrier is divided into two separate groups which are combined with separate reagent indicators, one of which also contains urea. The carriers are food soluble products, preferably sugar beads having a diameter of approximately 0.2 to 3.0 mm. The treated carriers and urea are encapsulated in a soluble capsule which is administered to a patient. The density of the carriers cause the capsule to migrate to the gastric mucosa, where the capsule, but not the reagents, is dissolved, placing the reagents and urea in direct contact with the gastric mucosa. The urea reacts with any urease present in the stomach by creating ammonia, which increases the pH in the immediate vicinity of the urea containing carrier and indicator beads. The two reagents react differently, through color change, to the increase in pH, which is viewed through use of an endoscope. A preferred first reagent is bromothymol blue (dibromothymolsulfonphthalein), which changes yellow in the presence of urease, and a preferred second reagent is phenol red (phenolsulfonphthalein), which turns red in the presence of urease.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

28. U.S. Patent No. 6,498,005 discloses a method of assaying an enzyme-mediated coupling reaction between a first and a second reactant. The method includes contacting the first

reactant with the second reactant in the presence of the enzyme. The second reactant includes a thiol derivative to yield a first product including a thiol derivative. The thiol derivative is then detected in the first product.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

29. U.S. Patent No. 6,495,102 discloses an artificial nose having an array comprising at least a first dye and a second dye in combination and having a distinct spectral response to an analyte. In one embodiment, the first and second dyes are from the group comprising porphyrin, chlorin, chlorophyll, phthalocyanine, or salen. In a further embodiment, the first and second dyes are metalloporphyrins. The reference states that the disclosed invention is particularly useful in detecting metal ligating vapors. The reference further states that the disclosed array can be connected to a wavelength sensitive light detecting device. The reference further discloses that at least the first dye or the second dye is a porphyrin having a periphery and a superstructure bonded to the periphery thereof.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

30. U.S. Patent No. 6,642,016 discloses a biosensor comprises a unit, comprising a substrate and an enzyme, which when brought into contact with the substrate is adapted to affect the substrate so that its conductivity changes as a function of time and temperature, and an electric circuit. The unit is included as a component in said electric circuit and the electric circuit is activable by applying an electric field and/or a magnetic field over the same to generate a measurable signal which is dependent on the total resistance of the circuit. The invention also relates to the use of a biosensor, a label with such a biosensor and a method of indicating the status of a product with such a biosensor.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

31. U.S. Application No. 2003/0077680 discloses a system and method for detecting bacterial infections in the gastrointestinal tract. In one embodiment, the system includes a first composition separated from a second composition. The first composition contains urea in powdered form. The second composition, on the other hand, contains an indicator. A biopsy of a gastric sample is first contacted with the first composition and then placed in the second composition. The second composition indicates the presence of an enzyme that, in turn, indicates the presence of bacteria. In an alternative embodiment, a biopsy of a gastric sample is contacted with a single composition. The composition contains urea in a powdered form combined with a

dry indicator. Besides urea and a dry indicator, the composition can also contain an anti-caking agent.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

32. U.S. Application No. 2003/0129085 discloses an artificial nose having an array comprising at least a first dye and a second dye in combination and having a distinct spectral response to an analyte. In one embodiment, the first and second dyes are from the group comprising porphyrin, chlorin, chlorophyll, phthalocyanine, or salen. In a further embodiment, the first and second dyes are metalloporphyrins. The reference states that the disclosed invention is particularly useful in detecting metal ligating vapors. The reference states that the disclosed array can be connected to a wavelength sensitive light detecting device.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

33. U.S. Application No. 2003/0143112 discloses an artificial nose comprising an array, the array comprising at least a first dye and a second dye deposited directly onto a single support in a predetermined pattern combination, the combination of the dyes in the array having a distinct and direct spectral absorbance or reflectance response to distinct analytes, wherein the first dye and the second are selected from the group of dyes consisting of chemoresponsive dyes, and the second dye is distinct from the first dye.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

34. U.S. Application No. 2003/0166298 discloses an artificial nose comprising an array, the array comprising at least a first dye and a second dye deposited directly onto a single support in a predetermined pattern combination, the combination of dyes in the array having a distinct and direct spectral absorbance or reflectance response to distinct analytes comprising one or more parent analytes or their derivatives, and an oxidizing source to partially oxidize at least one distinct parent analyte to at least one corresponding derivative analyte of said parent analyte, the array at least in part having a stronger distinct and direct absorbance or reflectance response to the derivative analyte than to the corresponding parent analyte.

This reference does not teach the present invention, for example a device for detecting an analyte comprising an analyte-specific compound that binds to the analyte and produces a detectable compound in combination with a given substrate, said detectable compound producing

a response when exposed to at least two dyes, the response being stronger and more distinct than a response of the analyte when exposed to the at least two dyes.

Conclusion

In view of the foregoing, the Applicants respectfully request that the Petition to Make Special be granted and that the application be advanced for examination.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: March 29, 2004

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